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APR 2 9 2014

510(k) Summary

510 (k) Number: K131917

Date of Submission: April 29, 2014

Submitter:

IBRAMED EQUIPAMENTOS MEDICOS
Avenida Dr. Carlos Burgos 2800
Amparo – Sao Paulo – Brasil

TEL – 5519-3817-9633
FAX – 5519-7816-7980

Official Contact:

Tara Conrad
TechLink International Consulting
18851 NE 29th Avenue Suite 720
Aventura, FL 33180

TEL – (305) 377-0077

Common Name:	Powered Muscle Stimulator
Trade Name:	Neurodyn Compact; Neurodyn II
Classification:	Class II
Product Code:	GZJ; GZI; IPF
Classification Panel:	Neurology
Regulation Numbers:	21 CFR 890.5850
Substantial Equivalence:	K121369 Neurodyn/Aussie Powered Muscle Stimulator by Ibramed; K021100 300 PV Complete Electrotherapy System by EMPI

Indications for Use

Indications for FES waveform:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

Indications for TENS waveform:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post surgical pain

Indications for Russian waveform:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions

- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

Device Description

The device NEURODYN II is a four output channel stimulator, operated in power supply 100 to 240 V, 50-60 Hz, with independent controls, graphic display backlit blue, mechanical contact keyboard and ABS cabinet with acrylic cover.

Used in the following electrical current therapies:
TENS (Transcutaneous Electrical Nerve Stimulation)
FES (Functional Electrical Stimulation)
RUSSIAN CURRENT (Burst Modulated Medium Frequency)

Characteristics:

TENS: four 120mA peak to peak channels
FES: four 120mA peak to peak channels
RUSSIAN: four 120mA peak to peak channels
Electrical Feed: 100 a 240V (50/60Hz)
Input Power: 85VA
Temperature Range During Transport and Storage: 41 to 122°F
Environment Operating Temperature Range: 41 to 113°F

The device NEURODYN COMPACT is a two output channel stimulator, operated in power supply 100 to 240 V, 50-60 Hz, with independent controls, graphic display backlit blue, mechanical contact keyboard and ABS cabinet with acrylic cover.

Used in the following electrical current therapies:
TENS (Transcutaneous Electrical Nerve Stimulation)
FES (Functional Electrical Stimulation)
RUSSIAN CURRENT (Burst Modulated Medium Frequency)

Characteristics:

TENS: four 120mA peak to peak channels
FES: four 120mA peak to peak channels
RUSSIAN: four 120mA peak to peak channels
Electrical Feed: 100 a 240V (50/60Hz)
Input Power: 85VA
Temperature Range During Transport and Storage: 41 to 122°F
Environment Operating Temperature Range: 41 to 113°F

Device Comparison Table

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Device name	Neurodyn Compact	Neurodyn II	Neurodyn	300 PV Empi
K Number	Pending	Pending	K121369	K021100
Manufacturer	Ibramed	Ibramed	Ibramed	Empi
Indications for Use	As a FES device: Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.	As a FES device: Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.		As a FES device: Stimulation of muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait. As a NMES device: Retarding or preventing disuse atrophy Maintaining or increasing range of motion Reeducating muscles Relaxation of muscle spasm Increasing local blood circulation Prevention of venous thrombosis of the calf muscles immediately after surgery
	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain
			As an Interferential and Premodulated device: Symptomatic relief of chronic pain, acute post traumatic pain, or acute post traumatic surgical pain	As an Interferential This device is not been used as a predicate for the Interferential waveform
	As a Burst Modulated Alternating Current -	As a Burst Modulated Alternating Current -Russian	As a Burst Modulated Alternating Current -Russian	

	Russian device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education Maintaining or increasing range of motion	device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education Maintaining or increasing range of motion	device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education Maintaining or increasing range of motion	
			As a Burst Modulated Alternating Current (Aussie) device: Temporary relaxation of muscle spasms Prevention or retardation of disuse atrophy in post-injury type conditions Increase local blood circulation Muscle re-education	
			As a Microcurrent device: Symptomatic relief of chronic intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	
Technological characteristics Medium-frequency alternating current (MFAC)	Identical	Identical	Identical	Identical
Device Material	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display
Width (in)	6.89	6.89	14.6	9.75
Height	4.53	4.53	4.9	8.75
Depth	10.83	10.83	12.4	12.75
Number of Channels	2	4	4	4

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Temperature range during transport and storage	59°f-104°f	59°f-104°f	41°f-122°f	-40 to 158°F
Environment operating temperature range	41°f-113°f	41°f-113°f	41°F-113°F	50 to 104°F
Performance	Identical	Identical	Identical	Identical
Biocompatibility	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrodes
Mechanical safety	Identical	Identical	Identical	Identical
Anatomical Sites	Identical	Identical	Identical	Identical
Burst Modulated Alternating Current (Russian)	Yes	Yes	Yes	No
Burst Modulated Alternating Current (Aussie)	No	No	Yes	No
Interferential	No	No	Yes	Yes
Microcurrent	No	No	Yes	No
TENS	Yes	Yes	Yes	Yes
FES	Yes	Yes	No	Yes
Premodulated	No	No	Yes	Yes
Method of current isolation	Double Isolation	Double Isolation	Double Isolation	Double Isolation
Patient leakage control-normal condition	0.0347 mA	0.0347 mA	0.0508mA	0.0502mA
Patient leakage control-single fault condition	0.0162 mA	0.0162 mA	0.0252mA	0.0248mA
Software Microprocessor	Yes	Yes	Yes	Yes
Automatic overload trip	No	No	No	No
Automatic shut off	No	No	No	No
Locking feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature
Treatment timer	Treatment timer with auto shut off	Treatment timer with auto shut off	Treatment timer with auto shut off	Treatment timer
Safety standards requirements biocompatibility	IEC 60601-1 IEC 60601-2 IEC 60602-10 IEC 60101-1-4	IEC 60601-1 IEC 60601-2 IEC 60602-10 IEC 60101-1-4	IEC 60601-1 IEC 60601-2 IEC 60602-10	IEC 60601-1 IEC 60601-2 IEC 60602-10
Chemical Composition	Has no Chemical Composition	Has no Chemical Composition	Has no Chemical Composition	Has no Chemical Composition
Energy Source	100 to 240 Volts 50/60Hz	100 to 240 Volts 50/60Hz	100 to 240 Volts 50/60Hz	3.0 DC
Electrical Output Parameters	TENS 0 to 120mA peak to peak FES 0 to 120mA peak to peak RUSSIA 0 to 120mA peak to peak	TENS 0 to 120mA peak to peak FES 0 to 120mA peak to peak RUSSIA 0 to 120mA peak to peak	FES 0 to 120mA peak to peak RUSSIA 0 to 120mA peak to peak Interferential 0 to 120mA peak to peak Aussie 0 to 120mA peak to peak Micro current 0 to 990µA peak	NMES 0 to 100mA peak to peak TENS 0 to 50mA peak to peak HV 0 to 300V peak
Frequency	0.5-250 Hz	0.5-250 Hz	0.5-250 Hz	0.5-150 Hz

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Phase Duration	50-500µs	50-500µs	50-500µs	50-400 µs
Current Output	124 mA @500Ω 110mA @2KΩ 39.2mA @10KΩ	124 mA @500Ω 110mA @2KΩ 39.2mA @10KΩ	125 mA @500Ω 95mA @2KΩ 23mA @10KΩ	200@ 500Ω 115@ 2KΩ 25@ 10KΩ
Charge per Phase	58µC	58µC	56µC	40@ 500Ω
Max. avg. power density	0.038W/cm2	0.038W/cm2	0.037W/cm^2	0.0088W/cm^2

Substantial Equivalence

The subject and the predicate devices have the same intended use, the same operating principle, and are similar in their hardware configuration.

Technology

The Neurodyn II and Neurodyn Compact devices are powered muscle stimulator machines that operate using the TENS, Russian and FES waveforms.

Non-Clinical Testing

This submission includes testing results of the Neurodyn II and Neurodyn Compact.

The devices have been tested according to:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-2-10

IEC 60601-1: The general standard IEC 60601-1 – Medical equipment/medical electrical equipment - Part 1: General requirements for basic safety and essential performance - gives general requirements of the series of standards. It is used as a bench mark for many electrical medical devices. Both the subject and predicate devices comply with this standard.

The standard contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. For certain types of medical electrical equipment, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

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This collateral standard applies to electromagnetic compatibility of medical electrical equipment and medical electrical systems. The object of this collateral standard is to specify general requirements and tests for electromagnetic compatibility of medical electrical equipment and medical electrical systems. They are in addition to the requirements of the general standard and serve as the basis for particular standards. Both the subject and predicate devices comply with this standard.

IEC 60601-2-10: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

IEC 60601-2-10:2012 specifies the requirements for the safety and essential performance of nerve and muscle stimulators, for use in the practice of physical medicine. This includes transcutaneous electrical nerve stimulators (TENS) and electrical muscle stimulators (EMS). This second edition cancels and replaces the first edition, published in 1987 and its Amendment 1 (2001). This edition constitutes a technical revision and is aligned with IEC 60601-1:2005+A1:2012.

IEC 60601-1-4: Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems

Specifies requirements for the process by which a programmable electrical medical system is designed. Serves as the basis of requirements of Particular Standards, including serving as a guide to safety requirements for the purpose of reducing and managing risk. This standard covers requirement specification, architecture, detailed design and implementation software development, modification, verification and validation, marking and accompanying documents.

Conclusion

The Neurodyn Compact and Neurodyn II machines are substantially equivalent to the currently legally marketed Neurodyn and 300 PV. The non-clinical testing demonstrates that the subject devices are as safe, as effective and perform as well or better than the legally marketed predicated devices. The IEC testing showed that the subject devices comply with Medical Electrical Device requirements for powered muscle stimulators. The subject devices passed all aspects of the clinical tests. This shows compliance with the standards currently in place for such medical devices. Compliance includes but is not limited to electrical safety (power input, electrical classification, limitation of voltage/energy, etc.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

Ibramed Equipamentos Medicos
c/o Ms. Tara Conrad
TechLink International Consulting
18851 NE 29th Avenue Suite 720
Aventura, FL 33180

Re: K131917
Trade Name: Neurodyn Compact and Neurodyn II
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, GZI
Dated: April 14, 2014
Received: April 18, 2014

Dear Ms. Conrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131917

Device Name
Neurodyn Compact and Neurodyn II

Indications for Use *(Describe)*

Indications for FES waveform:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

Indications for TENS waveform:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post surgical pain

Indications for Russian waveform:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.29 17:54:29 -04'00'

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